IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/629,077
Applicant:	Nancy Usiak et al.
Filed:	July 29, 2003
Title:	DEVICE AND METHOD FOR LOADING A LUMINAL GRAFT FOR ENDOLUMINAL DELIVERY
T.C./A.U.:	3734
Examiner:	Michael G. Mendoza
Confirmation No.:	5948
Docket No.:	BSI-513US

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES OR IN A NAFTA OR WTO MEMBER COUNTRY TO OVERCOME CITED PATENT OR PUBLICATION (37 C. F R. § 1.131)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PURPOSE OF DECLARATION

1. This Declaration is to establish completion of the invention of this application in the United States at a date prior to **April 25, 2003**, that is the effective date of the prior art publication that was cited by the examiner.

2. The person making this declaration are:

☐ the inventor(s).
☒ only some of the joint inventor(s).
☐ the party in interest.

3. To establish the date of completion of the invention of this application, the following attached document and/or models are submitted as evidence:

Disclosure document number 02-D0471, completed and executed by the inventors prior to the effective date of the prior art publication.

TIME OF PRESENTATION OF THE DECLARATION

4. This declaration is submitted prior to final rejection.

DECLARATION

I, James Weldon, declare that:

5. I am one of the inventors of the device and method disclosed and claimed in U.S. Patent Application Serial No. 10/629,077, entitled "Device and Method for Loading Graft for Endoluminal Delivery", that was filed in the United States Patent and Trademark Office on July 29, 2003.

6. Exhibit 1 is a copy of Disclosure document number 02-D0471 ("the Invention Disclosure") that discloses the above-referenced invention, redacted to remove evidence of dates.

7. The Invention Disclosure includes photographs of the claimed invention, providing evidence that the invention had been actually reduced to practice at the time of the drafting of the Invention Disclosure.

8. I have reviewed an unredacted copy of the Invention Disclosure and aver that the Invention Disclosure was drafted and signed by all inventors prior to April 25, 2003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Dated: 24 April 2008
attached.

BSC INVENTION DISCLOSURE

Boston Scientific Corporation
One Boston Scientific Place, Natick, MA 01760-1537

DISCLOSURE #:	02-0047
Date Received:	[redacted]
Tech Code:	
- For Legal Dept. use only -	

TITLE

Device and Method for Loading a Vascular Graft for Endovascular Delivery

DIVISION: Medi-Tech DATE: [redacted]

This confidential invention disclosure is submitted to the Legal Department by the inventor(s) as a request for legal services such as, a patentability opinion and/or seeking patent protection, and is thus subject to the Attorney-Client privilege.

INVENTORS

NANCY USIAK
MEDI-TECH
Home Address: 95 Magoun Ave. Medford, MA 02155
Business Phone: 617 972 4516
E-mail: usiakn@bsci.com

Signature & Date [redacted]

PAUL DiCARLO
MEDI-TECH
Home Address: 10 Starrett Ave Middleboro, Ma 02347
Business Phone: 617 972 4764
E-mail: Dicarlop@bsci.com

Signature & Date [redacted]

BOB RIOUX
MEDI-TECH
Home Address: 20 Woodridge Lane Ashland, Ma 01721
Business Phone 617-972-4536
E-mail: Riouxb@bsci.com

Signature & Date [redacted]

ADDITIONAL INVENTOR SIGNATURES ON PAGE 2

[redacted]
WITNESS
(Read & Understood)
GEORGE BOURNE
BSC Phone: (617) 972-4125

Signature & Date

ABSTRACT & FIGURES

(Please summarize the invention as it relates to the present state of the art and the disease condition.)

The present state of the art in the management of aortic aneurysms lies in the use of vascular grafts and stent grafts. Vascular grafts are current considered the gold standard device for repair; but stent grafts are preferred in high-risk patents. However, due to adverse events associated with stent grafts the ideal situation would be to devise a means of deliver vascular grafts in a percutaneous or endovascular manner.

This invention disclosure discusses a device and method that enable the endovascular and percutaneous delivery of vascular grafts. More specifically the concept is a device that rolls the textile graft uniformly about the graft axis, while maintaining its longitudinal dimension into a rod-like structure (figure 1a-1d). Once rolled, the graft is placed in a temporary cover, and can be loaded into any endovascular or transit delivery system. Once the graft is loaded within the delivery system, the temporary cover is removed and the graft is deployed.

The specific advantage of this invention lies in its ability to replace an invasive surgical procedure with a minimally invasive paradigm that is both elegant and practical. It offers the interventionalist the opportunity to minimize risk, trauma, cost and time – *the four essential components of less invasive medicine.*

Figure 1: System and method for rolling a vascular graft into a temporarily constrainment for endovascular or percutaneous delivery.

Figure 1a

Figure 1c

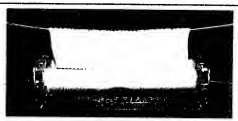

Figure 1b

Figure 1d

Keywords: IntraVascular, trans-lumen, graft, delivery, graft loading, rolling

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NANCY USIAK
MEDI-TECH
Home Address: 95 Magoun Ave, Medford MA 02155
Business Phone: 617 972 4516
E-mail: usiakn@bsci.com

Signature & Date [redacted]

PAUL DiCARLO
MEDI-TECH
Home Address: 10 Starrett Ave Middleboro, Ma
Business Phone: 617 972 4764
E-mail: Dicarlop@bsci.com

Signature & Date [redacted]

BOB RIOUX
MEDI-TECH
Home Address: 20 Woodridge Lane Ashland, Ma 01721
Business Phone: 617 972-4536
E-mail: Rouxb@bsci.com

Signature & Date [redacted]

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Figure 1a

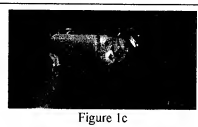

Figure 1c

Figure 1b

Figure 1d

Keywords: IntraVascular, trans-lumen, graft, delivery, graft loading, rolling

BACKGROUND

Please discuss the disease conditions and the present state of the art related to your invention including any existing devices, therapies, applications, manufacturing processes, etc.

INVENTOR continued

Kristian DiMatteo
MEDI-TECH
Home Address
Business Phone: 617-972-4661
E-mail: dimattek@bsci.com
Signature & Date

James Weldon
MEDI-TECH
Home Address
Business Phone: 617-972-4264
E-mail: weldonj@bsci.com
Signature & Date

Shubhang Mishra
MEDI-TECH
Home Address: See Back Page
Business Phone: 508-652-5761
E-mail: mishras@bsci.com
Signature & Date

Conventional surgical treatment of abdominal aortic aneurysms (AAA) typically takes the form of arterial re-constructive surgery. Here, a transabdominal or retroperitoneal approach is applied to replace the aneurysmal aortic segment with an in-line aortic bypass graft of appropriate size and length. This is typically fabricated from a biocompatible material that is thin-walled and compliant. Synthetic fibers such as those manufactured under the trademarks DACRON or TEFLON have been found to be suitable for the construction of the graft.

The graft is sutured into the non-aneurysmal arterial wall at the proximal and distal ends of the aneurysm. Although this procedure has demonstrated high rates of success with an operative mortality rate of only 3 to 5 %, the potential for trauma and adverse events remains high. In addition, the average length of hospital stay following such procedures ranges from five to 12 days – *an expensive component to procedural costs.* Furthermore, a complete recovery can take anywhere from a few weeks to 12 months. Thus, the need for a less traumatic option for the delivery and placement of endografts is paramount.

BSC invention disclosure 01-D0278 discusses a plurality of embodiments relating to the endo-vascular/laproscopic delivery, placement, and fixation of a vascular graft. In that disclosure, the method of compressing the graft into the endovascular delivery sheath, however, remains unclear. As such, this invention disclosure discusses the specific embodiments of a device that enables smooth, unfrayed compression of a vascular graft into a catheter sheath for endovascular delivery.

US Patent 6015422 (Kerr 2000) discusses the concept of a collapsible low-profile vascular graft implantation instrument and method for use thereof. The preferred embodiment of this invention applies the use of two angiographic guidewires bent to define two spaced-apart loops being dimensioned to support a vascular graft in a semi expanded state. However, it does not discuss how the graft is configured, compressed and constrained in the aforementioned manner. To that respect, the proposed invention enhances BSC position, and adds competitive value to BSC strategy by enabling the said Kerr method.

Additional advantages of this invention are that it is cheaply manufacturable by the vendor, and relatively affordable by the end user. In addition, it advances the ubiquitous paradigm of less invasive medicine, reducing risk, trauma, cost and time.

BACKGROUND

Please discuss the disease conditions and the present state of the art related to your invention including any existing devices, therapies, applications, manufacturing processes, etc.

INVENTORS continued

KRISTIAN DIMATTEO
MEDI-TECH
Home Address:
Business Phone: 617-972-4661
E-mail: dimattek@bsci.com

Signature & Date

JAMES WELDON
MEDI-TECH
Home Address:
Business Phone: 617-[redacted]
E-mail: weldonj@bsci.com

Signature & Date

SHUBHANG MISHRA
MEDI-TECH
Home Address: 30 Wildwood Drive
Southborough, Ma 01772
Business Phone: 508-652-5761
E-mail: mishras@bsci.com

Signature & Date [redacted]

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EXEMPLARY EMBODIMENTS

In detail, please describe the specific features of your idea/invention including, design, applications, operation, process, materials, coatings, and method of use and manufacture. Please attach any relevant figures, sketches, diagrams, CAD drawings, notebook pages, and any other supporting material that supplements your idea/invention. Please include an index of figures if necessary.

Please address the field of application and the specific advantages related to BSC devices, concepts and strategic position.

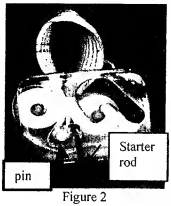

Figure 2

The preferred embodiment of this invention disclosure consists of a rolling fixture with two rollers and a belt, where the distance between the rollers is sized to the thickness of the most common vascular graft. The graft is rolled on a pin that is placed on the inside of the graft; (see Figure 2), which will acts as a placeholder for the delivery system. A starter rod helps the graft start the rolling process by compressing the graft up against the belt. Once the graft is rolled 2-3 revolutions the graft will occupy a large section of the pocket formed by the belt. This causes an increased loading on the belt that allows the starter rod to be removed. Once the graft is rolled up completely, and a temporary covering is placed on the graft, as seen in Figure 1d. The system is ready to be loaded into a delivery catheter. This basic configuration can be used to compress any textile tubular graft and because it pulls the graft directly down into the belt and compressed it, the graft maintains its length.

The temporary covering can be made of a paper with an adhesive edge that wraps around the graft at least one revolution with an overlap that adheres to itself.

ALTERNATE EMBODIMENTS

Please disclose any alternate embodiments of your idea/invention addressing the following points: Designs, applications, materials, coatings, uses, accessories, construction processes, costs, etc. Put yourself in the competitor's shoes and try to identify any alternate ways you could work around the examplary embodiment. Also, please assess the applicability of your idea/invention with other BSC products, procedures, and processes.

ALTERNATE DESIGNS

1. Another embodiment is the addition of a tensioning spring assembly to roller "A" of Figure 3. This assembly would have a "hard stop", a belt and rollers roller A and B. When roller 'A' is closest to roller 'B' it accommodates a thin graft. When thicker graft are loaded between the rollers the springs is compress which allows the rollers to spread apart to accept the thicker graft, while maintaining tension on the graft. Concept sketch Figure 3a.

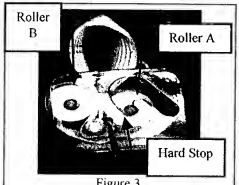

Figure 3

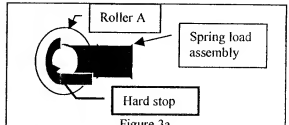

Figure 3a

2. Another embodiment in Figure 4 would replace the starter rod with one or more spring-loaded roller(s) X, which would tension the belt. As the graft is rolled the material is pulled into the pocket formed by the belt below the rollers 'A & B'. In most vascular cases the pocket has a preferred minimum diameter of 6 F (0.078") and a preferred maximum diameter of 28 F (0.364"), other applications may require different ranges.

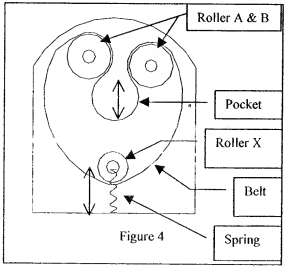

Figure 4

As the rolled graft increases in size, the springs attached to roller(s) X would expand maintaining tension on the belt, while allowing the pocket to increase in diameter. Conversely a smaller pocket would allow more belt length to be outside of rollers 'A & B', which would cause the spring to loosen or compress.

6. Another embodiment includes a hand crank to overcome the friction of the system and insure the roller turns at a constant rate to keep the graft from loading unevenly, see Figure 8. This could be used with any combination of embodiments.

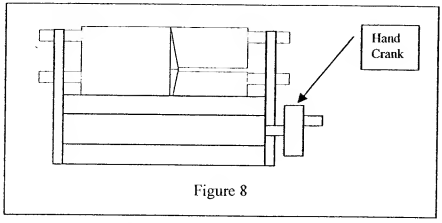

Figure 8

7. Another embodiment replaces the hand crank with an electric motor drive assembly.

8. Another embodiment uses a temporary peel away covering with a scoring or perforation to weaken the material in a desired region that can be removed as it is loaded into the delivery system.

9. Another embodiment uses a peel away covering with a scoring or perforation to weaken the material in a desired region that can be removed when the graft is delivered into the target region in the body.

10. Another embodiment uses an absorbable covering that can be absorbed away when the graft is delivered into the target region in the body.

11. Another embodiment allow the rolling fixture to accept a catheter or guide wire, the graft can then be rolled directly onto the device and constrained via an outer sheath, crocheting, suture, etc.

12. Another embodiment used in a bifurcated graft is the temporary fastening the two legs together prior to loading the graft into the fixture. Suturing, temporary adhesive, etc. can fasten the two legs together so the graft can then be loaded and roll in the same method as a tube graft.

13. Another embodiment using a bifurcated graft would involve pulling the leg into the body of the graft to minimize the length of the graft shown in Figure 9, then be loaded and roll in the same method as a tube graft.

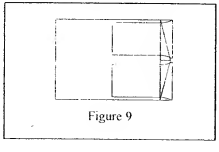

Figure 9

3. Another embodiment as shown in Figure 5 is a tensioning bar for the graft to maintain a straight constant feed, with evenly distributed tension.

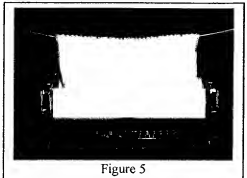

Figure 5

The tensioning system must follow the graft until it is almost completely rolled, then this tension system can be removed and the rolling of the graft completed.

4. Another embodiment allows for multiple a tensioning bars one in each leg of a bifurcated graft to maintain a straight constant feed, with evenly distributed tension.

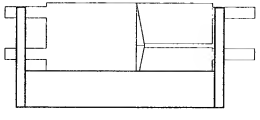

Figure 6

Each tensioning rod would be removed as the leg material of the graft is in the rollers and the rod begins to interfere with the rolling of the graft. See Figure 6.

5. Another embodiment utilizes another type of pin, the graft is placed in the relief of the rod and atraumatically held in place by the two fingers of the lock (see Figure 7). This design allows the graft to be roller down to the smallest size, because the first wrap is tight. At least one side of the rod must be removable in order for the temporarily restrained graft can be removed from the pin for loading. The center rod in the lock is optional but adds stability to the assembly.

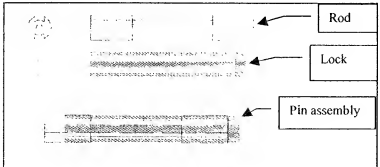

Figure 7

14. Another embodiment is a modification of the rolling process that places the pin on the outside of the graft and the graft is rolled around the pin. A starter mandrel or an atraumatic pin (see Figure 7) maybe required to orient the graft as it is rolled up.

ALTERNATE MATERIALS / COATINGS

1. The graft could be non-textile or a combination of textile and another material (for example Teflon).

2. Another material that can be used for the temporary covering is an absorbable material that can be absorbed away in the delivery system or as the device is being constrained while loading prior to deployment.

ALTERNATE APPLICATIONS

1. Use of this concept on a stent graft.

OTHER

GENERAL INFORMATION

Documentation of Idea:

Lab Notebook No. W725 Page No. 156 Other: -

Please list the names of people to whom and when you have disclosed your invention/idea.

Project Phase:

Product release date: - Engineering Project Number: -

If there has been a disclosure of your idea outside of BSC or if you plan on disclosing your idea outside of BSC within the next 90 days, please contact the Legal Department

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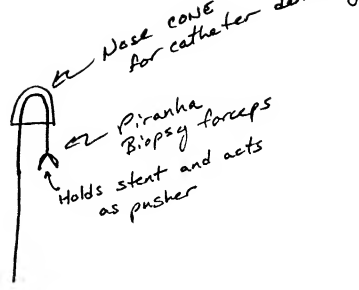
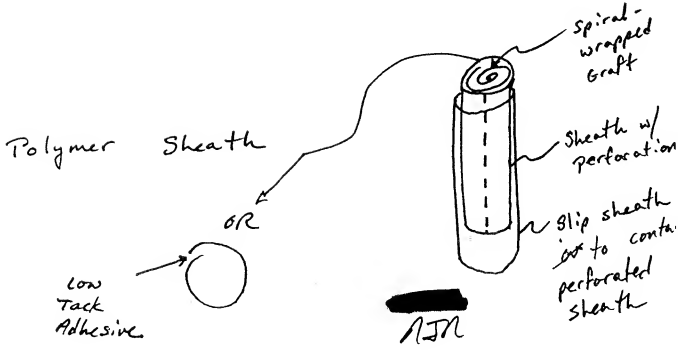

Nose cone for catheter delivery
Piranha Biopsy forceps
Holds stent and acts as pusher


Spiral-wrapped Graft
Polymer Sheath
Sheath w/ perforation
OR
Slip sheath over to conta
perforated sheath
Low Tack Adhesive
NJM